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GRAIN INSPECTION, PACKERS AND
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STOP 3630
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CHAPTER 5

NIRT MONITORING PROGRAM

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5.1 GENERAL INFORMATION

a. Wheat Protein. The protein monitoring program is designed to monitor the accuracy of official wheat protein testing services. Protein accuracy is evaluated by comparing field office and specified service point results with ISE results. Field offices with NIRT instruments may conduct supplemental file sample monitoring of specified service points within the circuit in addition to ISE monitoring to measure the performance of instruments and technicians.

Monitoring information is used by specified service points to evaluate the performance of their protein testing program. Field offices use the monitoring information to evaluate their own protein accuracy as well as the accuracy of the protein testing service program within their circuit. ISE uses the monitoring information to evaluate the accuracy of individual field locations as well as the entire program.

ISE monitoring results will identify service points generating questionable protein results. Field offices and specified service points must initiate corrective action and follow up whenever wheat protein testing problems are detected. Corrective action and follow-up includes investigating, identifying, correcting, and documenting the cause of protein accuracy problems.

Several methods are utilized to monitor particular elements in the protein testing process. These methods include quality control charts for file samples monitored, prepared samples, intermarket sample exchanges, and special studies. Procedures regarding these monitoring methods are discussed in the following sections.

b. Soybean Protein and Oil. The protein and oil check sample program is designed to monitor the accuracy of official soybean protein and oil testing services. Protein and oil accuracy is evaluated by comparing field office and specified service point results with ISE results.

Check sample information is used by field offices and inspection agencies to evaluate the performance of their local protein and oil testing program. ISE uses the check sample information to evaluate the accuracy of individual field locations as well as the entire program. Local monitoring by the field office will identify service points having questionable protein and/or oil results for all NIRT operators in their circuit.

Field offices and specified service points must initiate corrective action and follow-up whenever soybean protein and/or oil testing problems are detected. Corrective action and follow-up includes investigating, identifying, correcting, and documenting the cause of protein and/or oil accuracy problems.

Several methods are utilized to monitor particular elements in the protein and oil testing process. These methods include local monitoring, check samples, opinion samples, intermarket sample exchanges, and special studies or collaboratives. Procedures regarding these monitoring methods are discussed in the following sections.

c. Corn Protein, Oil, and Starch. The protein, oil, and starch check sample program is designed to monitor the accuracy of official corn protein, oil, and starch testing services. Protein, oil, and starch accuracy is evaluated by comparing field office and specified service point results with ISE results.

Check sample information is used by field offices and inspection agencies to evaluate the performance of their local testing program. ISE uses the check sample information to evaluate the accuracy of individual field locations as well as the entire program.

Local monitoring by the field office will identify service points having questionable protein, oil, and/or starch results for all NIRT operators in their circuit. Field offices and specified service points must initiate corrective action and follow-up whenever corn protein, oil, and/or starch problems are detected. Corrective action and follow-up includes investigating, identifying, correcting, and documenting the cause of protein, oil, and/or starch accuracy problems.

Several methods are utilized to monitor particular elements in the protein, oil, and starch testing process. These methods include local monitoring, check samples, opinion samples, intermarket sample exchanges, and special studies or collaboratives. Procedures regarding these monitoring methods are discussed in the following sections.

5.2 MONITORING REFERENCE SAMPLES

Daily SRS results will be monitored to evaluate instrument accuracy, bias adjustment procedures, and technician consistency. In addition, this information will be used to determine sources of error and formulate corrective action. All locations must submit a copy of SRS information recorded for each weekly period to the monitoring field office. The field office manager may request SRS information more frequently if a problem is suspected.

a. SRS Sample Monitoring Frequency. ISE, monitoring field offices, and specified service points record the results of daily and weekly standard reference sample checks on the standard reference sample form (examples are shown in Chapter 3). Specified service points and field office NIRT coordinators shall review these forms for accuracy and completeness.

b. Evaluation of Results. NIRT coordinators will evaluate the SRS test results to determine if: (1) bias adjustments were completed when necessary, (2) instrument accuracy was maintained, or (3) bias adjustments were required frequently (which may indicate the need for operator training, instrument repair, or SRS replacement).

5.3 MONITORING WHEAT FILE SAMPLES

Wheat protein accuracy is evaluated through the official monitoring system. Official inspection points will select and forward samples to ISE. Protein accuracy is determined by comparing original protein results with the average of the ISE master instruments results.

Agencies and field offices will initiate follow-up action when protein testing deficiencies (absolute, tolerance, or run limit violations) are detected by the monitoring program. Official agencies shall forward samples selected for the field office's supplemental monitoring program to the designated field office location.

a. Selecting Samples. Specified service points and field offices providing original protein testing services shall use the following procedures to select monitor samples. Select five wheat samples per class tested, per week, representing the range of protein observed during the week. Include a low and a high protein sample each week with three intermediate samples. Avoid selecting all samples tested from the same day. When less than five samples per class are tested during a week, select all samples tested for that class. Do not make up monitoring samples to fulfill the minimum number of samples. Do not select mixed wheat samples.

Each dockage free sample submitted for monitoring must be at least 500 grams unless special arrangements have been made with ISE.

Field offices and/or ISE may request additional samples for monitoring and/or special study purposes.

b. Mailing Instructions. Seal the samples in individual 6-mil plastic bags. Mark the sample number and wheat class on each bag using an indelible marker. Place the samples and sample information (scan sheet) in a canvas mailing bag and indicate "Protein Monitoring Sample" on the reverse side of the mail tag (use an orange color mailing tag). This will assist in separating protein monitoring samples from other samples received in the mail. According to postal requirements, Federal employees must use metered mailing tags. All nonfederal employees (i.e., delegated and designated agencies) must use business reply mailing tags.

c. Monitoring Results. Field office personnel must retrieve the monitoring data from the Quality Assurance/Quality Control (QAQC) homepage, review the information, and immediately initiate follow-up action when accuracy deficiencies are indicated by monitoring results. In addition, field office managers must forward ISE monitoring results to the specified service points for their review and follow-up action within 2 working days of retrieval.

d. Evaluating Monitoring Results. Field offices and specified service points will evaluate completed quality control charts to determine if any action limit (tolerance limits, absolute limits, and/or run limit) violations occurred.

Action limit violations occurring on the average difference chart generally indicate a bias-related problem. Action limit violations occurring on the range difference chart generally indicate inconsistency due to fluctuating laboratory conditions, failure to follow procedures consistently, instrument problems, or improper instrument slope or bias adjustment. Violations on the range difference chart are actually more serious than those on the average difference chart because if the results are inconsistent, the average differences are not meaningful.

Monitoring field offices and agencies must initiate corrective action when quality control chart rule violations occur. Field office managers must document any action taken to resolve the differences. This documentation includes action taken to identify the cause and extent of the problem and steps to resolve the problem and/or reasons why no further action is necessary. Documentation may be placed directly on the control chart indicating action limit violations.

5.4 LOCAL NIRT MONITORING

Field offices may conduct periodic or routine file sample monitoring of official laboratories providing testing (soybean protein and oil, and/or corn protein, oil, and starch) in their circuit to measure the performance of instruments and technicians. ISE will advise the field on developing a local monitoring program and assist in analyzing and interpreting the data.

5.5 NIRT CHECK SAMPLES

Check samples are used to test the capability of the national soybean protein and oil, and the corn protein, oil, and starch testing programs. Soybean check samples are issued twice per year and corn check samples are issued once per year (prior to harvest) by ISE. Specified service points and laboratories that provide soybean protein and oil, and/or corn protein, oil, and starch testing services for FGIS must participate in the check sample program.

Check samples originate from ISE and will include specific instructions for testing the samples. Upon receipt, inspection points must complete the analysis of these samples within 10 working days. Report check sample results to ISE on the forms provided. Whenever possible, the results should be faxed to ISE to expedite the preparation of the check sample report.

The field will be notified immediately if the test results indicate a problem at a test location. Otherwise, ISE will not release any information on the content of the check samples until the results from all laboratories have been received. ISE will analyze the data and issue a report which will be distributed to all participating official agencies and supervising field offices.

When requested, field offices will assist ISE in obtaining bulk soybean or corn samples to be used in the check sample program.

5.6 WHEAT QUALITY CONTROL CHARTS

a. General. A Quality Control Chart (QCC) is a visual display of monitoring data. A QCC effectively displays extreme variations, shifts, and trends. Also, a QCC illustrates the difference between results while statistically defining expected variability using control limits. These limits are established based on the normal expected variation of results.

b. Control Charts. The protein monitoring program utilizes Average Difference and Range Difference quality control charts. The average difference chart illustrates the difference between a specified service point's average for five weekly monitoring samples and the ISE's average for the same samples. The range difference chart plots the range of individual sample differences for the corresponding weekly monitoring sample set.

(1) Average Difference Chart. The average difference chart includes a zero or Center Line (CL), upper and lower Tolerance Limits (TL), and upper and lower Absolute Limit lines (AL).

The center line is the control chart reference point. Points plotted above the center line indicate a positive difference when compared to the monitoring result. Points plotted below the center line indicate a negative difference when compared to the monitoring result. The absolute limit lines are set at $\pm$ 0.20 percent protein from the center line. The tolerance limit lines are set at $\pm$ 0.15 percent protein from the center line.

These tolerances are determined statistically based on the systems actual performance and may be revised from time to time. A violation of any of the established tolerances means that there is less than one chance in one hundred that the observed error level occurred due to random chance. Therefore, it is very likely that a correctable problem exists.

(2) Range Difference Chart. The range difference chart indicates how much difference is observed within a set of monitoring samples. The absolute limit line is set at 0.60 percent protein. The tolerance limit line is set at 0.40 percent protein.

Average and Range Difference control charts are shown in Figures 1 and 2.

c. Plotting Control Charts. Control charts are generated as follows.

(1) Sequential Plotting. Control charts depict how a process or system is varying over time. In order for the results to be meaningful, data is plotted in the sequence in which the original results were obtained. That is, when plotting the Average/Range chart, samples originally tested during week 3 are plotted after samples originally tested during week 2, but before samples originally tested during week 4 (**see Figures 1 and 2**).

(2) Average Difference. The difference between the original average result and the monitoring average results is obtained by subtracting the monitoring office result from the original protein result (**see example**).

(3) Range Difference. The difference between the original result and the monitoring result is determined for each individual sample monitored within a sample set. The range difference value that is plotted is the difference between the smallest and the largest difference observed in one set. If these two differences are of the opposite sign, add the magnitudes of the two numbers. The range difference is calculated and plotted on the range difference chart.

(4) Plotted Results. The difference between the monitoring average result and the original result obtained from step 2 is plotted on the average difference chart. The positive differences (original results higher in protein then the monitoring results) are plotted above the center line. Negative differences (original results lower in protein then the monitoring results) are plotted below the center line. Results having no difference (original result is identical to monitoring result) are plotted on the center line.

Example of Plotting Control Chart

Week Ending Date	Sample No.	Original Protein	ISE Protein	ORIG-ISE Difference
6/28/99	1	13.15	13.07	+0.08
6/28/99	2	10.18	10.54	-0.36
6/28/99	3	14.47	14.79	-0.32
6/28/99	4	12.56	12.23	+0.33
6/28/99	5	18.57	18.77	-0.20
	Average	13.79	13.88	-0.09

In the example, the average difference between the service point and ISE is -0.09.

The range difference is calculated by determining the largest spread between the individual sample differences. In this example, the largest difference is +0.33 for sample No. 4 and -0.36 for sample No. 2. The spread or range between these two numbers is 0.69. Therefore, 0.69 is the range difference. Figures 1 and 2 illustrate average and range difference charts.

d. Action Limits. Protein testing problems are indicated on the control charts either by a large difference between the average protein results or a consistent pattern of smaller differences on a series of average results. Three action limits are used for rapid identification of protein testing problems through interpretation of the control chart.

(1) Absolute Limit (AL). This action limit is intended to identify excessive differences between results and indicates a potential protein testing problem. An absolute limit violation occurs if any plotted value is equal to or greater than the absolute limit lines.

Absolute limit lines are set at $\pm$ 0.20 percent protein for the average protein results. The range result absolute limit line is set at 0.60 percent protein for the protein range difference.

(2) Tolerance Limit (TL). This action limit controls the number of consecutive data sets with a large difference between original and monitoring results but not so large as to exceed the absolute limit.

An average difference limit violation occurs if two consecutive data sets are either equal to or above the upper tolerance limit line or both equal to or below the lower tolerance limit line. The average difference tolerance limits are set at $\pm$ 0.15 percent protein.

A range difference tolerance limit violation occurs if two consecutive data sets are equal to or greater than the tolerance limit. The range difference tolerance limit is set at 0.40 percent protein.

(3) Run Limit. This action limit controls the number of consecutive comparisons which are all above or all below the average difference chart center line (CL). A violation occurs if four out of five consecutive results are either all above or all below the CL, and the average difference from the center line for these four results exceed 0.10 percent protein. Run limits do not apply to the range difference chart.

5.7 COLLABORATIVE CHECK SAMPLES AND SPECIAL STUDIES

a. Collaborative Check Samples. Collaborative check samples may be initiated by ISE for cross-checking other data. ISE will select and send enough of each sample selected so that specified service points can retain a portion for rechecking purposes. Upon receipt, participants must complete the analysis and report the data within 5 working days.

Use the forms provided with the samples to report analysis results. Retain a copy of the completed form and return the original immediately to ISE. Results from all locations included in the collaborative study will be compiled by ISE and reported to participating field offices and specified service points.

b. Special Studies. ISE may initiate and conduct special studies. These studies are designed for a specific purpose (i.e., resolving differences either within or between markets, evaluating calibration performance, or updating the calibrations). When special studies are initiated by ISE, it is required that all participants (as designated by ISE) respond with utmost priority, as these are normally of an urgent nature and an expedient resolution of the problem is essential. Because ISE will not be routinely monitoring soybean or corn file samples, the field will be required to provide ISE with samples for monitoring and updating the calibration. Periodically throughout the year, ISE will contact selected field offices in soybean and corn markets and request that ten randomly selected soybean samples be provided to monitor calibration performance.

During harvest, ISE will request those field locations providing corn and soybean NIRT services to collect samples within specified ranges of protein, oil, and starch for use in updating the calibrations. Prior to harvest, ISE will notify the field of the types and numbers of samples needed and instructions for shipping them to ISE.

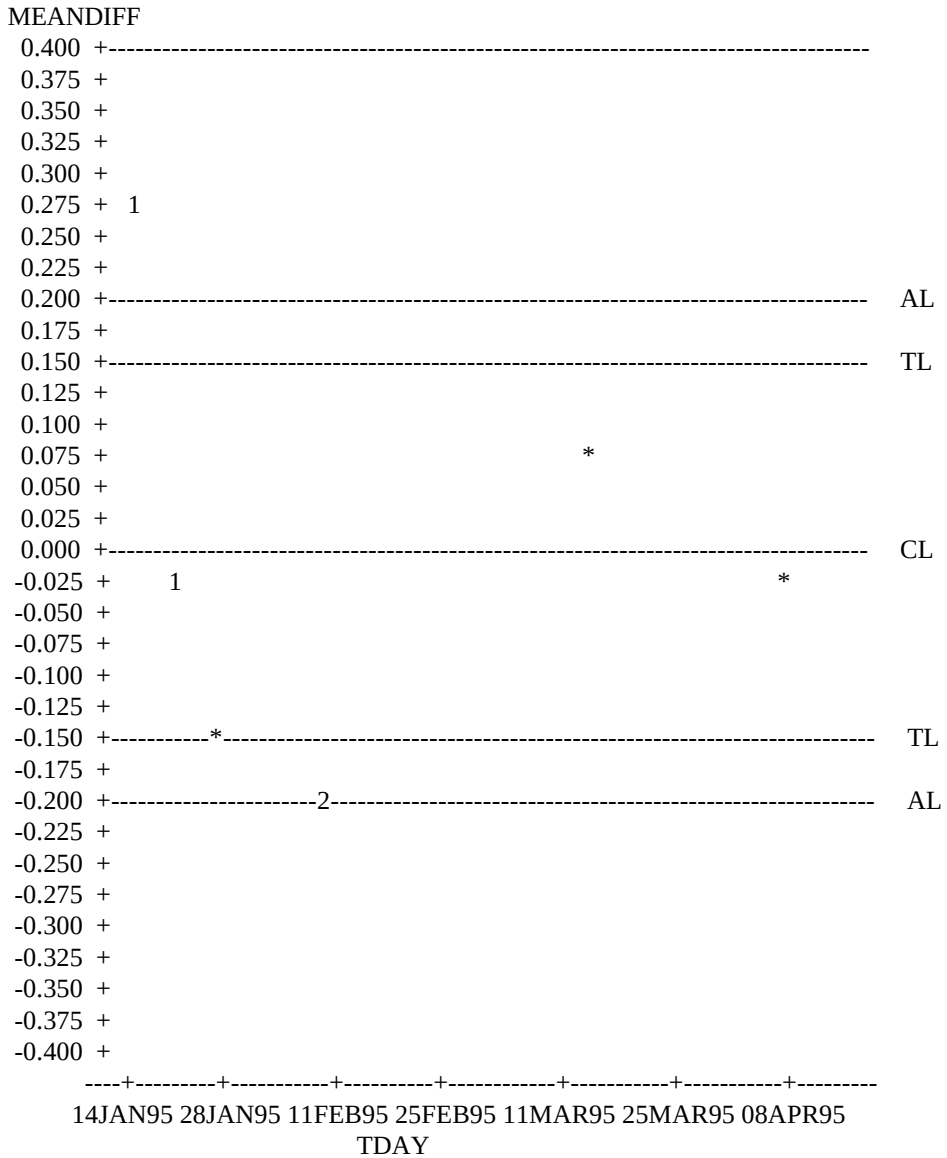
5.8 INTERMARKET SAMPLE EXCHANGE

An intermarket sample exchange helps isolate protein and/or oil differences between inspection points. Protein and oil testing laboratories will determine protein and oil results on separate portions obtained from the same sample. Protein and oil results are then compared to determine if any significant differences exist.

There are no restrictions as to which offices may exchange samples. Specified service points are encouraged to exchange samples with other specified service points and field offices for the purpose of resolving intermarket inspection differences. A copy of the results of the exchange must be provided to the field office and/or ISE for review if they were not participants in the exchange.

Figure 1

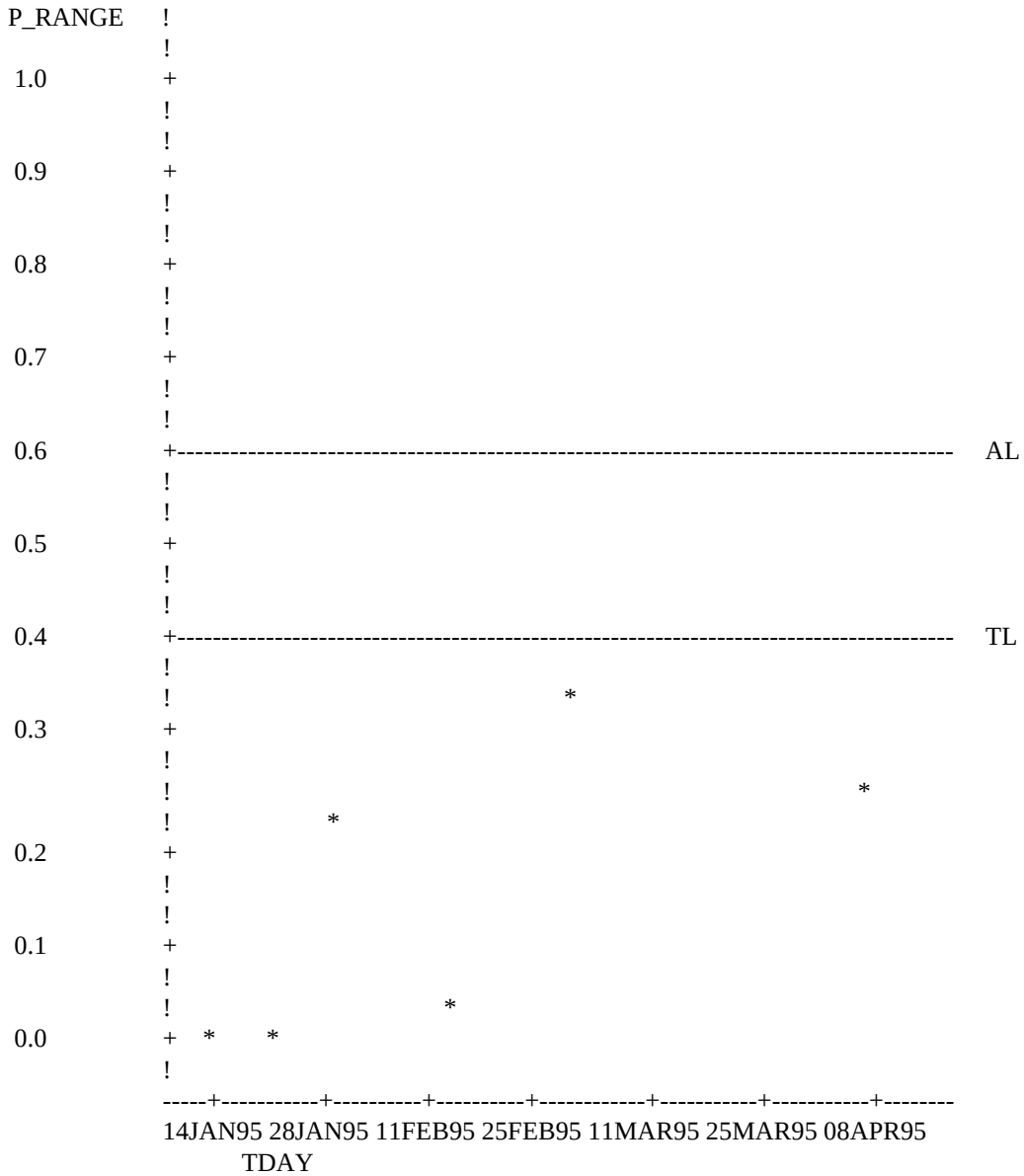
AVERAGE DIFFERENCE BETWEEN FIELD LOCATION AND ISE
180-DAY PERIOD



AL = Absolute Limit
TL = Tolerance Limit
CL = Center Line
* = Average of 5 samples
1,2,3, or 4 = Number of samples averaged

Figure 2

RANGE DIFFERENCE BETWEEN FIELD LOCATION AND ISE
180-DAY PERIOD



AL = Absolute Limit TL = Tolerance Limit